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Alert | Litigation

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New Erythritol Study Creates Potential Litigation Exposure for Makers, Sellers of Erythritol-Containing Products

Go-To Guide:

- According to a recent study, there is an association between erythritol and cardiovascular risks, including heart attacks, clotting, and strokes.
- Although erythritol's current status is Generally Recognized as Safe (GRAS) based on various erythritol suppliers' self-affirmed GRAS assessments, that status may be challenged by litigants or subject to reexamination given the findings of the recent study.
- Manufacturers and sellers of erythritol and erythritol-containing products should be aware of a heightened risk of litigation exposure due to the study's findings, including personal injury, economic loss, and medical monitoring claims, potentially in consolidated proceedings.
- Those who make and sell erythritol-containing products should consider adopting risk-mitigation strategies in light of the new regulatory and litigation risks presented by the study.

I. FDA Regulation of Food Additives and Erythritol's Regulatory Status

The U.S. Food and Drug Administration (FDA) regulates food and food additives. The Federal Food, Drug & Cosmetic Act (FD&C Act) requires that food additives meet the FDA's premarket approval requirements prior to being used in foods. However, the FD&C Act specifically exempts substances that have been "Generally Recognized as Safe" (GRAS) from the definition of "food additive," and therefore from the premarket approval requirements. 21 U.S.C. § 321(s); *see also* 21 C.F.R. § 170.30 (defining eligibility for GRAS status).

Erythritol—a polyol (sugar alcohol) found in fruits and vegetables, and naturally created in the human body—is a popular artificial sweetener found in many foods. Although no specific law or regulation has identified erythritol as GRAS, numerous ingredient suppliers have submitted notices to the FDA indicating that erythritol was *self-affirmed* GRAS. *See* 21 C.F.R. § 170.205. Six such GRAS notifications have been submitted to the FDA since 2001 and have obtained a response that the FDA had "no questions" regarding the notifier's GRAS determination based on both the information the notifier provided and other information available to the FDA.

Significantly, the FDA does not formally approve GRAS notifications. Its historical response of "no questions" indicates that the agency has to date expressed no concerns regarding the safety of erythritol for use in foods and beverages. Nevertheless, "[n]ew information may at any time require reconsideration of the GRAS status of a food ingredient." 21 C.F.R. § 170.30(l).

II. The New Study Concerning Erythritol

A study published in Nature Medicine Feb. 27, titled *The Artificial Sweetener Erythritol and Cardiovascular Event Risk* (the "Study"), claims erythritol is associated with an increased risk of cardiovascular events and calls for additional research on the long-term safety of erythritol. The Study's findings are based on a series of studies and tests:

- **Discovery cohort**. Untargeted three-year studies using plasma samples from patients undergoing diagnostic cardiac evaluation, the findings of which suggested an association between multiple polyols, including erythritol, and a risk of death, heart attack, and stroke.
- **Validation cohorts**. Targeted three-year studies examining a U.S. cohort of 2,149 people and a European cohort of 833 people enrolled at quaternary referral centers with high rates of cardiovascular problems. The Study found that in both cohorts, individuals with prevalent cardiovascular disease and those who experienced death, heart attack, or stroke over the three-year follow-up period had higher plasma levels of erythritol.
- **Intervention studies**. Lab testing revealed an increased platelet aggregation response to erythritol. The Study also found that where eight volunteers were given a drink sweetened with 30 grams of erythritol, the levels of erythritol in their plasma were 1,000-fold higher than their baseline levels for hours afterwards.

As its authors themselves noted, the Study has multiple limitations, including:

- An overnight fasting level of erythritol was measured only once at enrollment, and the value of successive measurements for determining incident cardiovascular risks is unknown.
- The individuals followed in both cohorts had high prevalence of cardiovascular risk factors, such that it is unclear how the Study's findings would translate to the general population.

- The cohort studies, by design, show only *association*, not a *causal link*, between erythritol and adverse cardiovascular events.
- Unmodelled confounding factors, such as diet, may have affected the Study's results.

Responses to the Study have emphasized its participants—many of whom already had cardiovascular risk factors—and the lack of a causal link between erythritol and cardiovascular events. Others have highlighted both prior scientific research demonstrating erythritol's safety, including in the six GRAS notifications submitted to the FDA, and acceptance of erythritol by global regulatory bodies.

III. Litigation Exposure and Anticipated Litigation Activity

Various news outlets have picked up and reported on the Study since its publication, including The New York Times, The Washington Post, Forbes, and CNN. Further, plaintiffs' firms have begun posting about the Study on their websites and offering to speak with those who have ingested erythritol and suffered a heart attack, stroke, or cardiac damage about the possibility of filing a lawsuit. Given the abundant use of erythritol and the current (and anticipated) legal advertisements based on the Study, personal injury suits, consumer class actions, and multi-district or consolidated proceedings surrounding erythritol are potential risks.

Similar studies that have identified a previously unreported putative association between a food product and alleged health risks can drive media reporting, attorney advertising, and public fears past the state of the science, sometimes resulting in commencement of litigation with little grounding in fact. The potential ramp-up of litigation activity may include:

- **Personal injury cases**. Consumers who have ingested erythritol or erythritol-containing products and *have* experienced heart attacks, strokes, clotting, and/or death may bring personal injury lawsuits under theories of tort and product liability law against the manufacturers and sellers of those products. Because no causal association is yet known or knowable, these lawsuits are based on mere correlation and, when accompanied by plaintiffs' advertising, can rapidly grow into dozens, hundreds, or thousands regardless of the absence of any scientific or medical basis to believe an individual consumer's health issues resulted from their individual ingestion of erythritol-containing products.
- **Consumer class actions**. Consumers who claim they would not have purchased erythritol or erythritol-containing products if they had known of the alleged risks posed by erythritol may also bring economic loss claims against the manufacturers and sellers of those products, with potential causes of action arising under state statutes and common law theories including breach of express or implied warranty, fraud, and unjust enrichment. Plaintiffs in such lawsuits typically assert that they should receive full or partial refunds of all purchases involving such previously undisclosed risks, on the theory that the asserted risks reduce or negate the value of the product at the time of purchase.
- **Medical monitoring class actions**. Consumers who have ingested erythritol or erythritol-containing products and have *not* experienced heart attacks, strokes, clotting, and/or death may file suit against manufacturers and sellers of those products, claiming that they are now at an increased risk of experiencing heart attacks, strokes, clotting, and/or death due to their ingestion of erythritol and seeking to recover from these entities the expense of monitoring or testing for these adverse events. Although medical monitoring as a remedy is not well-suited to address mere associational studies of this type and is intended to be used in circumstances where a specific geographic population is exposed to a known carcinogenic hazard (e.g., a toxic chemical spill), plaintiffs increasingly assert medical monitoring suits as an alternative strategy to assert speculative health risks when there exists the lack of causation evidence.

In support of their claims, potential litigants may allege that erythritol and erythritol-containing products are "adulterated," as they are or contain an unsafe food additive. *See* 21 U.S.C. § 342(a)(2)(c)(i) (providing that a food is deemed "adulterated" "if it is or if it bears or contains . . . any food additive that is unsafe"). As evidenced by the GRAS notifications submitted to the FDA and the agency's consistent "no questions" response thereto, erythritol is currently GRAS. However, there is a risk that plaintiffs will argue, based on the Study, that erythritol has never been safe and *should not have been considered* GRAS, and all erythritol-containing foods have been adulterated. Plaintiffs may also argue going forward that following the Study's publication, erythritol-containing foods should *no longer* be considered GRAS and therefore should no longer be sold. Plaintiffs or their proxies have increasingly used citizen's petitions to the FDA as a supplemental tool to initiate agency action that can provide additional fodder for private suits.

IV. Potential Risk-Mitigation Strategies

In response to the Study, manufacturers and sellers of erythritol and erythritol-containing products may consider adopting strategies to mitigate their litigation exposure. Potential risk-mitigating measures may include:

- **Alternative Product Formulations**. In light of the potential litigation exposure and the concern that the Study—or an accumulation of such studies—could influence the FDA to reconsider erythritol's current status as GRAS, those who manufacture or sell erythritol-containing products may consider the feasibility of using a different ingredient or product formulation.
- **Fielding Consumer Complaints and Adverse Event Claims**. Manufacturers and sellers of products containing erythritol may also consider crafting a strategy by which to collect and respond quickly and effectively to complaints from consumers and adverse event claims concerning such products. A public relations strategy designed to respond promptly to customer questions, educate consumers regarding the Study and what it does (and does not) mean, and displace fears with facts, may help stem the flow of potential litigants.
- **Considering Evidence of Regulatory Compliance**. In some states, food manufacturers and sellers may rely on their compliance with federal and state regulations as evidence that their product is not defective. Although plaintiffs' attorneys may try to deflect such evidence based on erythritol's *self-affirmed* GRAS status, entities who make and sell erythritol and erythritol-containing products should consider collecting and preserving documentation of the regulatory compliance of their products to introduce as evidence.
- **Evaluating Indemnification Possibilities**. Manufacturers and sellers of products containing erythritol may consider reviewing their relationships with others in the chain of supply and distribution of such products to identify potential common law, statutory, and contractual indemnification pathways available to them, as well as indemnification risks to others in the chain of distribution.

Conclusion

Although erythritol currently enjoys GRAS status, manufacturers and sellers of products containing erythritol should be aware of the Study and the new litigation risks arising out of it, and respond accordingly.

Authors

This GT Alert was prepared by:

- Gregory E. Ostfeld | +1 312.476.5056 | ostfeldg@gtlaw.com
- Justin J. Prochnow | +1 303.572.6562 | prochnowjj@gtlaw.com
- Angelica Halat | +1 973.360.7900 | halata@gtlaw.com